



PTO/SB/03A (22-03)  
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Substitute for form 1442/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 17

### Complete if Known

Application Number	10/669,251
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00102

### U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
KW	1	US- 4,021,472 A	05/1977	Fujii et al.	
KW	2	US- 4,051,842 A	10/1977	Hazel et al.	
KW	3	US- 4,140,122 A	02/1979	Kuhl et al.	
KW	4	US- 4,224,342 A	09/1980	Fujii et al.	
KW	5	US- 4,283,418 A	08/1981	Fuji et al.	
KW	6	US- 4,310,533 A	01/1982	Uegai et al.	
	7	US- 4,383,529 A	05/1983	Webster	
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KW	9	US- 4,657,763 A	04/1987	Finkelstein	
KW	10	US- 4,668,504 A	05/1987	Kahan et al.	
KW	11	US- 4,711,848 A	12/1987	Insley et al.	
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KW	13	US- 4,732,973 A	03/1988	Barr et al.	
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KW	15	US- 4,788,603 A	11/1988	Fujimura et al.	
KW	16	US- 4,829,052 A	05/1989	Glover et al.	
KW	17	US- 4,839,283 A	06/1989	Kawasaki et al.	
KW	18	US- 4,843,094 A	06/1989	Imaki et al.	
KW	19	US- 4,889,723 A	12/1989	Kim et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>4</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
KW	20	WO 94/07525	04/1994			
KW	21	WO 95/28422	10/1995			
KW	22	WO 95/34538	12/1995			
KW	23	WO 96/12021	04/1996			
KW	24	WO 96/14067	05/1996			
	25	WO 97/03679	02/1997			

Examiner  
Signature

/Kevin Weddington/ (02/15/2006)

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Sheet 2 of 17

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Application Number	10/669,251
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KW	26	US- 4,931,279 A	06/1990	Bawa et al.	
	27	US- 4,963,654 A	10/1990	Katunuma	
	28	US- 5,004,612 A	04/1991	Kim et al.	
	29	US- 5,077,428 A	12/1991	Imaki et al.	
	30	US- 5,110,602 A	05/1992	Kim et al.	
	31	US- 5,157,019 A	10/1992	Glover et al.	
	32	US- 5,166,134 A	11/1992	Lezdey et al.	
	33	US- 5,175,253 A	12/1992	Fallon et al.	
	34	US- 5,214,191 A	05/1993	Kirschenheuter et al	
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**FOREIGN PATENT DOCUMENTS**

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KW	45	WO 97/09346	03/1997			
	46	WO 97/09347	03/1997			
	47	WO 97/10222	03/1997			
	48	WO 97/10231	03/1997			
	49	WO 97/21690	06/1997			
KW	50	WO 97/24339	07/1997			

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/Kevin Weddington/ (02/15/2006)

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Sheet 3 of 17**Complete if Known**

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First Named Inventor	Leland SHAPIRO
Art Unit	3736
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Attorney Docket Number	330310.00102

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		Number-Kind Code <sup>2</sup> (if known)			
X	51	US- 5,486,470 A	01/1996	Darke et al.	
	52	US- 5,489,593 A	02/1996	Palmer et al.	
	53	US- 5,504,094 A	04/1996	Nakane et al.	
	54	US- 5,514,653 A	05/1996	Perlmutter	
	55	US- 5,514,713 A	05/1996	Nakai et al.	
	56	US- 5,529,920 A	06/1996	Cole et al.	
	57	US- 5,532,215 A	07/1996	Lezdey et al.	
	58	US- 5,565,334 A	10/1996	Kufe et al.	
	59	US- 5,567,682 A	10/1996	Pert	
	60	US- 5,593,858 A	01/1997	Fleer et al.	
	61	US- 5,604,201 A	02/1997	Thomas et al.	
	62	US- 5,610,140 A	03/1997	Goodfellow et al.	
	63	US- 5,610,285 A	03/1997	Lebing et al.	
	64	US- 5,614,555 A	03/1997	Nakai et al.	
	65	US- 5,616,693 A	04/1997	Hwang et al.	
	66	US- 5,618,792 A	04/1997	Gyorkos et al.	
	67	US- 5,622,984 A	04/1997	Nakai et al.	
	68	US- 5,635,593 A	06/1997	Cheronis et al.	
/w	69	US- 5,641,670 A	06/1997	Treco et al.	

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
K	70	WO 97/31937	09/1997			
	71	WO 97/33996	09/1997			
	72	WO 97/37969	10/1997			
	73	WO 97/45402	12/1997			
	74	WO 97/48706	12/1997			
KO	75	WO 97/49679	12/1997			

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 4 of 17

**Complete if Known**

Application Number	10/669,251
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00102

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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W	76	US- 5,663,416 A	09/1997	Kirschenheuter et al	
	77	US- 5,665,589 A	09/1997	Harris et al.	
	78	US- 5,700,779 A	12/1997	Goodfellow et al.	
	79	US- 5,710,026 A	01/1998	Sprecher	
	80	US- 5,712,117 A	01/1998	Sprecher	
	81	US- 5,747,645 A	05/1998	Sprecher	
	82	US- 5,750,506 A	05/1998	Goodfellow et al.	
	83	US- 5,759,548 A	06/1998	Bathurst et al.	
	84	US- 5,780,009 A	07/1998	Karatzas et al.	
	85	US- 5,798,442 A	08/1998	Gallant et al.	
	86	US- 5,801,148 A	09/1998	Gyorkos et al.	
	87	US- 5,804,594 A	09/1998	Murad	
	88	US- 5,807,829 A	09/1998	Gyorkos et al.	
	89	US- 5,811,241 A	09/1998	Goodfellow et al.	
	90	US- 5,817,484 A	10/1998	Yu et al.	
	91	US- 5,834,431 A	11/1998	Stewart et al.	
	92	US- 5,843,900 A	12/1998	Cheronis et al.	
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	94	US- 5,861,299 A	01/1999	Archibald et al.	

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W	95	WO 98/06417	02/1998			
	96	WO 98/09206	03/1998			
	97	WO 98/20034	05/1998			
	98	WO 98/21186	05/1998			
	99	WO 98/22098	05/1998			
	100	WO 98/22619	05/1998			

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		Filing Date	September 25, 2003		
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Sheet	5	of	17	Attorney Docket Number	330310.00102

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W	101	US- 5,861,380 A	01/1999	Gyorkos et al.	
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	104	US- 5,874,424 A	02/1999	Batchelor et al.	
	105	US- 5,874,585 A	02/1999	Gyorkos et al.	
	106	US- 5,891,852 A	04/1999	Gyorkos et al.	
	107	US- 5,914,342 A	06/1999	Maurer et al.	
	108	US- 6,127,356 A	10/2000	Crapo et al.	
	109	US- 6,140,116 A	10/2000	Dinsmore et al.	
	110	US- 6,235,714 B1	05/2001	Paul et al.	
W	111	US- 6,323,219 B1	11/2001	Costanzo	
	224	US- 5,281,617 A	01/1994	Kirschenheuter et al	
	225	US- 5,314,910 A	05/1994	Kirschenheuter et al	
	226	US- 5,376,655 A	12/1994	Imaki et al.	
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W	112	WO 98/23565	06/1998			
	113	WO 98/24806	06/1998			
	114	WO 98/46597	10/1998			
	115	WO 98/49190	11/1998			
W	116	WO 98/50342	11/1998			
	117	WO 98/50420	11/1998			

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
W	122	Aoki H, Akaike T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacystatin, a proteinase inhibitor in rice, against herpes simplex virus type 1 in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.	
	123	Auerswald et al., "Recombinant leech-derived trypsin inhibitor: construction, production, protein chemical characterization and inhibition of HIV-1 replication", Biol Chem Hoppe Seyler, 375(10):695-703 (1994).	
	124	Avril LE, Di Martino-Ferrer M, Barin F, Gauthier F., "Interaction between a membrane-associated serine proteinase of U-937 monocytes and peptides from the V3 loop of the human immunodeficiency virus type 1 (HIV-1) gp120 envelope glycoprotein", FEBS Lett, 317(1-2):167-72 (Feb. 8, 1993).	
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		Application Number	10/669,251		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	3736		
		Examiner Name	Not Yet Assigned		
Sheet	8	of	17	Attorney Docket Number	330310.00102

NON PATENT LITERATURE DOCUMENTS			
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Kw	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.	
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. B.--The Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5; p. 249 (1954).	
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la	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).		
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lw	151	Szeghy G, Kenyeres B. On the therapy of herpes simplex keratitis with heparin and trypsin. [Article in German] Klin Monatsbl Augenheilkd 1968; 153(6):827-30.		

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llw	152	Cilberto et al., 1985, Cell, 41:531-540.	
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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
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		Examiner Name	Not Yet Assigned		
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	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
	164	Pryor, W. A. et al., in Chem Biol Interact 1985, 54, 171.	
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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
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Ig	172	Schini et al. in Circ Res 1994, 74, 24.	
I	173	Meki, A. R. et al. in Toxicon 1998, 36, 18519.	
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	177	Remington's Pharmaceutical Sciences, 1990, p. 1519-1675, Gennaro, A.R., ed., Mack Publishing Company, Easton, PA.	
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[Signature]	182	Scharpe et al., "Protease and their inhibitors: today and tomorrow", 1991, Biochimie, 73(1):121-126.	
	183	Kido et al., "A novel membrane-bound serine esterase in human T4+ lymphocytes immunologically reactive with antibody inhibiting syncytia induced by HIV-1. Purification and characterization", J Biol Chem., 1990, 265(35):21979-85.	
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>			
		Application Number	10/669,251		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	3736		
		Examiner Name	Not Yet Assigned		
Sheet	15	of	17	Attorney Docket Number	330310.00102

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
W	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
	203	Zhimov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.	
	204	Chesnokova N.B. et al., "Antiproteases in herpetic keratitis", Metab Pediatr Syst Ophthalmol, 1986;9(1):593-6.	
	205	Adelman S.F. et al., "Protease inhibitors suppress fibrinolytic activity of herpesvirus-transformed cells", J Gen Virol, 1982, 60(Pt 1):15-24.	
	206	Chesnokova N.B. et al., "Main proteolytic inhibitors in ocular herpes", Vopr Med Khim, 1981, 27(5):663-5.	
	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.	
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.	
	209	Estaquier J., "Fas-mediated apoptosis of CD4+ and CD8+ T cells from human immunodeficiency virus-infected persons: differential in vitro preventive effect of cytokines and protease antagonists", 1996, Blood, 15;87(12):4959-66.	
	210	Shimizu, T. et al., "DNA Fragmentation induced by Protease Activation in P53-null Human Leukemia HL60 Cells Undergoing Apoptosis Following Treatment with the Topoisomerase I Inhibitor Camptothecin: Cell-Free System Studies", 1996, Exp Cell Res, 1:226(2):292-301.	
A	211	Glynn et al., "Apoptosis induced by HIV Infection in H9 T Cells is Blocked by ICE-Family Protease Inhibition but not by a FAS(CD95) Antagonist", 1996, J. Immunol, 1: 157(7):2754-2758.	

Examiner Signature	/Kevin Weddington/ (02/15/2006)	Date Considered	
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Substitute for form 1442/PTO  <b>INFORMATION DISCLOSURE  STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/669,251
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	3736
				Examiner Name	Not Yet Assigned
Sheet	16	of	17	Attorney Docket Number	330310.00102

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
lc	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antitrypsin Deficiency", 1999, Am J Respir Cell Mol Biol, 1;20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64).	
	215	Lima et al., "Mucosal injury and disruption of intestinal barrier function in HIV-infected individuals with and without diarrhea and cryptosporidiosis in northeast Brazil", 1997, Am J Gastroenterol, 92(10):1861-6.	
	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepidymitis", 1990, Antibiot. Khimioter, 35(7):50-52.	
	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9).	

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/669,251
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00102

Sheet

17

of

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LC	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
LC	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	

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